REMARKS

The March 24, 2008 Official Action has been carefully considered. In view of the amendment submitted herewith and these remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set in the March 24, 2008 Official Action. The initial due date for response, therefore, was June 24, 2008. A petition for a two (2) month extension of the response period is presented with this Amendment and Request for Reconsideration, which is being filed before expiration of the two (2) month extension period.

It is also noted preliminarily that as a result of the requirements for restriction and election of species set forth in the Official Action dated November 29, 2007, claims 3-32 have been withdrawn from consideration in this application. Applicants reiterate that their election of the subject matter of claims 1 and 2, and the compounds of Formula VII, in response to the aforementioned requirements was without prejudice to their right to file one or more divisional applications, as provided in 35 USC §121, directed to any subject matter held finally withdrawn from consideration in this application. Furthermore, in accordance with the decisions in *In re Ochiai*, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 37 USPQ2d 1663 (Fed. Cir. 1966), and the notice published in the Official Gazette on March 26, 1996, setting forth revised guidelines for the treatment of restricted product and process claims (see 1184 OG 86), applicants respectfully request that since the present restriction requirement has been made final, in the event the claims of elected Group I are found allowable, then the corresponding method of use claims be rejoined and examined for patentability. See §821.04 of the Manual of Patent Examining Procedure. Claims 3 and 31 have been amended to facilitate rejoinder of claims 3-10, 31 and 32.

In the March 24, 2008 Official Action, claims 1 and 2 stand rejected for allegedly failing to comply with the enablement requirement of 35 USC §112, first paragraph. In this connection, the examiner acknowledges that the specification is enabling for the treatment of viral infections using the triazinoindole compounds called for in claim 1, but contends there is insufficient enablement provided in the specification for prophylactic use of such compounds.

Claims 1 and 2 have been further rejected under 35 USC §102(b) as allegedly anticipated

by the abstract of Eshba et al., Pharmazie, 42: 664-666 (1987). The examiner specifically relies on structural Formula II of the Eshba et al. abstract in support of this rejection, and further notes, at page 5 of the Official Action, that "a composition comprising the same agents as the claimed composition will inherently possess the qualities recited herein".

The foregoing rejections constitute all of the grounds set forth in the March 24, 2008 Official Action for refusing the present application.

In accordance with the present amendment, original claims 1 and 2 have been cancelled, and replaced by new claims 33 and 34 which are drawn to the elected subject matter. As previously noted, the remaining claims have been withdrawn from consideration as a result of the aforementioned restriction requirement.

No new matter has been introduced into this application by reason of the present amendment, entry of which is respectfully requested.

For the reasons given below, applicants respectfully submit that the rejections of claims 1 and 2 based on alleged insufficient enablement and alleged anticipation by the abstract of Eshba et al. as set forth in the March 24, 2008 Official Action, lack merit and/or cannot be maintained in view of the present amendment. These grounds of rejection are, therefore, respectfully traversed.

A. The 35 USC §112, First Paragraph, Rejection of Claims 1 and 2 is Untenable in View of the Submission of New Claims 33 and 34

Applicants respectfully take exception to the examiner's contention that claims 1 and 2 fail to satisfy the enablement requirement of 35 USC §112, due to the recitation of "prophylaxis" therein. Nevertheless, in the interest of advancing prosecution of this application, and without acquiescing in the propriety of the rejection, claim 1 has been replaced by new claim 33, which omits any reference to "prophylaxis". As now amended, the claimed compositions are characterized as being "for treatment of viral infections". The examiner has acknowledged that the specification is enabling for the treatment of viral infections with the recited triazinoindole compounds. Consequently, this ground of rejection is believed to be overcome by the present amendment.

The cancellation of claims 1 and 2 is without prejudice to applicants' right to file one or

more divisional applications with respect to the subject matter of those claims, as provided in 35 USC §121.

For the foregoing reasons, it is respectfully requested that the 35 USC §112, first paragraph, rejection of claims 1 and 2, as set forth in the March 24 Official Action, be withdrawn upon reconsideration.

B. The Anticipation Rejection of Claims 1 and 2 Based on the Abstract of Eshba et al. is Untenable for Failure to Comply with the Requirements of 35 USC §102(b)

Rejections under 35 USC §102 are proper only when the claimed subject matter is identically disclosed or described in the reference cited as evidence of anticipation. *In re Arkley*, 172 USPQ 524 (CCPA 1972). Applying this rule of law to the present case, the 35 USC §102(b) rejection of claims 1 and 2 based on the abstract of Eshba et al. is plainly improper because the subject matter of the rejected claims is nowhere identically disclosed or described in the cited reference.

The compounds of Formula II of the abstract of Eshba et al., which are specifically cited in support of this rejection, are characterized by the presence of an amino group at the 5-position of the pyrazole ring. The Markush group of substituents recited for the corresponding ring position of the compounds of the structural formula set forth in new claim 33 does not include an amino group. Accordingly, new claim 33 cannot be found to be anticipated by the disclosure of the Eshba et al. abstract.

Inasmuch as the Eshba et al. abstract fails to identically disclose or describe all of the claim recitations of applicants' claims 1 and 2, the §102(b) rejection of claims 1 and 2 based thereon is improper and should be withdrawn upon reconsideration.

Not only does the Eshba et al. abstract fail as an anticipation of the subject matter of new claims 33 and 34, but it fails to provide evidence of obviousness with respect to claims 33 and 34, as well. Applicants' position in this regard is squarely supported by the recent opinion of the Court of Appeals for the Federal Circuit in *Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd.*, 83 USPQ2d 1169 (Fed. Cir. 2007).

It is noteworthy that structural Formula II of the Eshba et al. abstract has an amino group

at the 5-position of the pyrazole ring. This stands in contrast to the structural formula of new claim 33, in which the corresponding substituent is a radical selected from the group consisting of hydrogen, alkyl, alkoxy, hydroxyalkyl, aryl and heteroaryl. The presence of an amino group is not specified. Thus, the abstract of Eshba et al. clearly fails to suggest the substituent groups called for in new claims 33 and 34. Nor does the Eshba et al. abstract provide any reason or motivation for one of ordinary skill in the art to arrive at the specific substituent groups recited in new claims 33 and 34. Consequently, the Eshba et al. abstract cannot reasonably be found to render the compounds claimed by applicants herein *prima facie* obvious, according to the test applied by the Federal Circuit in *Takeda, supra.* In that case, the Court stated that a finding of *prima facie* obviousness of a chemical compound requires that the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention. The Court went on to comment in this regard, as follows:

> That test for prima facie obviousness for chemical compounds is consistent with the legal principles enunciated in *KSR*. While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness inquiry, the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination, *KSR*, 127 S. Ct. at 1731. Moreover, the Court indicated that there is "no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis." *Id.* As long as the test is not applied as a "rigid and mandatory" formula, that test can provide "helpful insight" to an obviousness inquiry. *Id.* Thus, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound. [footnote omitted; emphasis added].

Id. at 1174.

In rejecting the defendant's obviousness argument in *Takeda*, the Court adopted the District Court's finding that there was "nothing in the prior art to suggest making the specific molecular modifications to [the most closely related prior art compound] that are necessary to achieve the claimed compounds". *Id.* at 1177. The molecular differences between applicants' claimed compounds and those of the Eshba et al. abstract are at least as patentably significant as those found to exist in *Takeda* (5-{4-[2-(5-ethyl-2-pyridyl)ethoxy] benzyl}-2,4-thiazolidinedione

vs. 5-{4-[2-(6-methyl-2-pyridyl)ethoxy]benzyl}-2,4-thiazolidinedione).

Moreover, in the present case, just as in *Takeda*, there is no disclosure in the cited reference to suggest to an artisan of ordinary skill that the removal of the amino group at the 5-position of pyrazole in the 1,2,4-triazino[5,6-b]indole derivatives described therein would bring about a reasonable expectation of success.

Furthermore, there is nothing in the text of the Eshba et al. abstract to indicate that the compounds of structural Formula II possess any anti-viral activity. The title of the abstract simply indicates that the 1,2,4-triazino[5,6-b]indole derivatives were synthesized as potential anti-viral agents. The abstract is totally silent as to whether or not the compounds of structural Formula II actually exhibited such activity. It is well-established that silence in a reference is not an adequate substitute for a disclosure of facts from which a conclusion of obviousness may justifiably follow. *In re Burt*, 148 USPQ 548 (CCPA 1966).

For all of the foregoing reasons, the conclusion is inescapable that the Eshba et al. abstract fails to teach or suggest the composition claimed in new claims 33 and 34. Accordingly, the 35 USC §102(b) rejection of claims 1 and 2 is inapplicable to new claims 33 and 34 and should, therefore, be withdrawn upon reconsideration.

In view of the present amendment and the foregoing remarks, it is respectfully requested that the rejections set forth in the March 24, 2008 Official Action be withdrawn and that this application be passed to issue and such action is earnestly solicited.

Respectfully submitted,

DANN DORFMAN HERRELL and SKILLMAN, P.C.

Attorneys for Applicant

By Patrick J. Hagan

Patrick J. Hagan
Registration No. 27,643

Customer Number 000110
(215) 563-4100 (telephone)
(215) 563-4044 (facsimile)
phagan@ddhs.com (email)